

**Notice of Allowability**

Application No.

10/715,559

Examiner

Krishnan S. Menon

Applicant(s)

YEN ET AL.

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE of 12/11/06.
2. ☒ The allowed claim(s) is/are 30 and 33-37; RENUMBERED 1-6.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Scott Brairton on 1/4/07.

The application has been amended as follows:

Amended Claims List follows, starting on a fresh page, below.

**Claims 30 and 33-37 are allowed.**

The following is an examiner's statement of reasons for allowance:

Even though the closest reference Denman teaches about separating various components of milk protein such as factor IX and includes pH adjustment as one of the 'stabilizing agent', her efforts are directed towards obtaining mainly LA-tPA using arginine as a stabilizer. Applicant's results of the recovery of factor IX in table 2 of the specification can be considered as "unexpected" with pH adjustment using only a buffer and without any other stabilizing agent, which would overcome the prima-facie case of obviousness over Denman.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Amended Claims List***

1-29(canceled).

30(currently amended). A method of purifying the human coagulation factor IX from animal milk, at least including the following procedures:

(a) ~~using buffer solution to adjust the pH value of the animal milk to a range between 5.0 and 6.5~~ stabilizing the human coagulation factor IX in transgenic animal milk while precipitating casein consisting essentially of adjusting the pH to a range between 5.0 and 6.5 using a buffer solution;

(b) processing the animal milk of the certain pH value obtained from Step (a) through a ceramic filtering membrane under a flow pressure between 10 psi and 20 psi, for the purpose of separating the casein from the milk while collecting the filtered solution

(c) processing the aforesaid filtered solution through polysulfone filtering membrane under a flow pressure between 10 psi and 20 psi and at a pH value of 5.0 and 6.5, for the purpose of concentrating the human coagulation factor IX while collecting the second concentrated solution and;

(d) processing the aforesaid concentrated solution by chromatographic process to purify the human coagulation factor IX.

Claims 31 and 32(canceled).

33(new). The method as claimed in claim 30, wherein the diameter of the holes of the aforesaid filtering membrane is between 0.1 $\mu$ m and 0.44 $\mu$ m.

34(new). The method as claimed in claim 30, wherein the diameter of the holes of the aforesaid filtering membrane is between 0.14 $\mu$ m and 0.2 $\mu$ m.

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35(new). The method as claimed in claim 30, wherein the aforesaid polysulfone filtering membrane has a molecular weight cut-off of 30kD.

36(new). The method as claimed in claim 30, wherein the aforesaid chromatographic process is salt in, salt out, gel filtration, ion exchange chromatography or affinity chromatography.

37(new). The method as claimed in claim 30, wherein the aforesaid milk is whole milk, defatted milk or whey.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krishnan S Menon  
Primary Examiner  
Art Unit 1723